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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,675	07/14/2003	Maryellen L. Giger	239738US20	4119
22850	7590	07/17/2007		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER AKHAVANNIK, HADI	
			ART UNIT 2624	PAPER NUMBER
			NOTIFICATION DATE 07/17/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

**Office Action Summary**

Application No.

10/617,675

Applicant(s)

GIGER ET AL.

Examiner

Hadi Akhavannik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Response to Arguments***

1. Applicant has amended the independent claims to include "the prognosis of recovery includes an indication of the likelihood of survival". The examiner agrees that the previous rejection does not teach this limitation. However, prior art Ohno-Machado et al. (paper titled "Modular Neural Networks for Medical Prognosis: Quantifying the Benefits of Combining Neural Networks for Survival Prediction", referred to as "Machado" herein) discloses using neural networks to indicate the likelihood of survival of a patient.
2. Second, the applicant has submitted a statement of common ownership, which disqualifies the "Armato" patent. The examiner believes that this only renders the rejection of claim 14 moot and not claims 13 and 16, as applicant argues on page 11 of the remarks. This is because the Armato patent was only used on the rejection of claim 14 and 18-19.
3. For the rejection of claims 14 and 18-19, the examiner is using Ravdin et al (paper titled "A practical application of neural network analysis for predicting outcome of individual breast cancer patients") as it discloses using additional truth indicators such a lymph involvement in a prognosis result using a neural network.
4. Please see final rejection below.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-12, 15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (5657362, referred to as "Giger" herein) in view of Ohno-Machado et al. (paper titled "Modular Neural Networks for Medical Prognosis: Quantifying the Benefits of Combining Neural Networks for Survival Prediction", referred to as "Machado" herein)

Regarding claim 1, Giger discloses obtaining segmented image data of a portion of the medical image data corresponding to an abnormality (see abstract and column 4 lines 7-35 discloses receiving a segmented image of the breast);

extracting at least one abnormality feature from the segmented image data corresponding to the abnormality (column 6 lines 40-65 discloses extracting a lesion portion);

Giger discloses judging the quality of the abnormality feature in column 6 line 66 to column 7 line 15 but Giger does not explicitly disclose determining the prognosis which includes an indication of the likelihood of survival.

Machado discloses determining the prognosis of recovery, which includes the likelihood of survival (see abstract, figures 1-2, 8 and section titled "Materials and

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Methods", as it discloses using a classifier, where abnormality information is inputted, to determine the likelihood of survival and a prognosis of a patient).

It would have been obvious at the time of the invention to one of ordinary skill of the art to combine in Giger a prognosis method as taught by Machado. The reason for the combination is because it makes for a more robust system that is able to present an operator with a prognosis so to make for more efficient and accurate treatment planning. Also both inventions are from the same field of endeavor of medical analysis.

Regarding claim 2, the combination of Giger and Machado disclose obtaining segmented image data of a portion of the medical image data corresponding to a parenchymal region (see Giger column 7 lines 52-60 and column 8 lines 8-22 discloses examining a parenchymal region);

and extracting at least one parenchymal feature from the segmented image data corresponding to the parenchymal region (Giger, column 8 lines 8-15 discloses finding abnormalities in the parenchymal region),

wherein the determining step comprises determining the prognosis on recovery based additionally on the extracted at least one parenchymal feature (as noted in the rejection of claim 1, Giger discloses finding parenchymal features and Machado disclose a classifier that takes in abnormality information and produces a prognosis and likelihood of survival).

Regarding claim 17, please see the rejection of claim 2 above as it discloses all aspects of claim 17.

Regarding claim 3, Giger discloses determining the contrast corresponding the parenchymall region (see column 6 lines 53-65 disclosing finding intensity based features)

Regarding claim 4, Giger discloses in column 7 lines 34-60 that an image is received that includes but abnormalities and regions free from abnormalities. The data is analyzed to determine potential abnormalities.

Regarding claim 5, Giger discloses in column 6 line 66 to column 7 lines 33 discloses locating a region and performing region growing.

Regarding claim 6, Giger discloses mammographic image data (see abstract).

Regarding claim 7, Giger discloses radial gradient index (see column 6 lines 54-60)

Regarding claim 8, see Giger, column 7 lines 34-51 discloses dense portion analysis.

Regarding claim 9, see Giger, column 5 lines 15-33, disclose gray level of the ROI.

Regarding claim 10, Giger discloses determining speculation measure in column 8 lines 23-36.

Regarding claim 11, the rejection of claim 10 discloses determining the speculation based on histogram enhancement and edge enhancement.

Regarding claims 12 and 15, Giger discloses using an ANN in column 8 lines 1-5. Giger discloses using ANN on both the parenchymal and lesion region.

Regarding claims 18-19, please see column 1, lines 7-19 of Giger as it discloses the method is computerized.

6. Claims 13, 16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger in view of Machado as applied to claim 1 above and in further view of Huo et al. (6282305, referred to "Huo" herein).

Regarding claim 13, the rejection of claim 1 discloses all aspects of claim 13 except it does not explicitly disclose using a linear discriminant.

Huo discloses applying the extracted at least one abnormality feature to a linear discriminant that classifies the abnormality at an output of the linear discriminant (see column 17 line 46 to column 18 line 55 as it discloses using linear discriminant to classify an abnormality).

It would have been obvious at the time of the invention to one of ordinary skill in the art to include Machado and Giger a linear discriminant analysis (LDA) means as taught by Huo. The reason for the combination is because LDA is a well known and established statistical technique that can classify into two groups of cases (see motivation by Huo in column 17 lines 63-67).

Regarding claim 16, please see the rejection of claim 13 above as it discloses all aspects of claim 16.

Regarding claims 18-19, please see column 1, lines 7-19 of Giger as it discloses the method is computerized.

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7. Claims 14 and 18-19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giger in view of Machado as applied to claim 1 above and in further view of Ravdin et al. (paper titled "A practical application of neural network analysis for predicting outcome of individual breast cancer patients", referred to as "Ravdin" herein).

The rejection of claim 1 discloses all aspects of claim 14 except for using lymph node involvement as a truth indicator. Although, Machado does disclose using truth indicators in Table II.

Ravdin discloses including lymph node involvement on page 286 column 1.

It would have been obvious to one of ordinary skill in the art to include in Giger in view of Machado an additional truth table inclusion means as taught by Ravdin. The reason for the combination is because it makes for a more accurate system that gives a more informed assessment of the likelihood of survival of the subject.

Regarding claims 18-19, please see column 1, lines 7-19 of Giger as it discloses the method is computerized.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hadi Akhavannik whose telephone number is 571-272-8622. The examiner can normally be reached on 10:30-7:00.

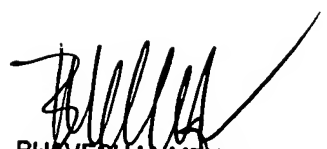
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh M. Mehta can be reached on (571)272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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BHAVESH M. MENTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 2600